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TITLE: A Double-Blind, Randomized Study of Safety and Efficacy of OnabotulinumtoxinA (OnaBoNT-A) versus Oral Oxybutynin in SCI Patients with NDO (11-09-10-04)

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14. ABSTRACT After initial difficulty recruiting, a revised IRB protocol that included a decrease in patient visits and the number of urodynamic studies was approved on August 22, 2013 which allows for mailing of letters to local spinal cord injured patients at MEDVAMC. One hundred letters were mailed out on October 1 <sup>st</sup> , 2013. Five responses have been received thus far, 2 calls from a VA brochure. One patient has qualified. Two other possible patients have been identified for the study as well. A second batch of 157 letters was mailed out on October 18 <sup>th</sup> , 2013.					
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Annual Report for W81XWH-12-1-0549 SC110198:  
A Double-Blind, Randomized Study of Safety and Efficacy of OnabotulinumtoxinA  
(OnaBoNT-A) versus Oral Oxybutynin in SCI Patients with NDO (11-09-10-04)

## INTRODUCTION

This is a Phase 3B, double-blind, randomized, placebo-controlled, parallel-group study to assess the safety and efficacy of onaBoNT-A or 15 mg per day of oral oxybutynin hydrochloride ER in spinal cord injured volunteers diagnosed with neurogenic detrusor overactivity. A total of 36 volunteers will be recruited for this study. Volunteers will include both males and females with spinal cord injuries who are 18 to 80 years of age and diagnosed with neurogenic detrusor overactivity. They are veterans who visit the Michael E. DeBakey Veterans Affairs Medical Center (MEDVAMC) in Houston, TX. There are no eligibility restrictions as to race or ethnicity.

Volunteers will be randomized using a blocked randomization approach designed by the statistician and implemented by the MEDVAMC Research Pharmacy to either: ARM 1: onaBoNT-A 200 U bladder injection and placebo oral capsule daily or ARM 2: Placebo bladder injection (saline) and oxybutynin ER 15mg capsule daily. Subjects will be randomized into one of the two treatment arms, using a block size of 4. The order in which the treatments are assigned in each block is randomized and this process is repeated for consecutive blocks of subjects until all subjects are randomized. This process ensures that after every fourth randomized subject, the number of subjects in each treatment group is equal. Volunteers will be on the study for approximately 36 weeks.

## OVERALL PROGRESS

The protocol received initial BCM IRB approval on June 15, 2013 and revised VA IRB approval on August 22, 2013.

After initial difficulty recruiting, a revised IRB protocol that included a decrease in patient visits and the number of urodynamic studies was approved on August 22, 2013 which allows for mailing of letters to local spinal cord injured patients at MEDVAMC. One hundred letters were mailed out on October 1<sup>st</sup>, 2013. Five responses have been received thus far, 2 calls from a VA brochure. One patient has qualified. Two other possible patients have been identified for the study as well. A second batch of 157 letters was mailed out on October 18<sup>th</sup>, 2013.

A current problem with patient recruitment has been addressed by revising the study protocol to include less patient visits and less frequent number of urodynamic studies. We have expanded our recruitment methods to include VA patient brochures in the spinal cord clinic, and patient mail outs. We are also attending a weekly SCI Urology meeting to directly interact with PMR staff regarding potential study candidates.

## WORK PLAN

Recruitment efforts will be enhanced through patient mail outs and direct interaction with Spinal Cord Injury PMR staff. The protocol's schedule of events will be followed.

## APPENDIX

The QuadChart forwarded to GOR